IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Sanganee et al.	Art Unit	: 1626
Patent No.	: 7,482,363	Examiner	: Joseph R. Kosack
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Serial No.	: 10/508,332		
Filed	: September 17, 2004		
Title	: PIPERIDINE DERIVATIVES USEFUL AS MODULATORS OF CHEMOKINE RECEPTOR ACTIVITY		

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APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Patentee hereby requests reconsideration of the Patent Term Adjustment (PTA) accorded to the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 784 to 1053 days is respectfully requested.

REMARKS

(1) Measuring Overlap of "A Delay" and "B Delay"

"A Delays" are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three-year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in Wyeth et al. v. Jon W. Dudas (U.S. District Court, D.C., CA No. 07-1492, Mem. Op. September 30, 2008, 580 F.Supp.2d 138; 88 USPQ2d 1538), the only way that these periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The Wyeth v. Dudas court

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determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." "B delay" begins only after the PTO has failed to issue a patent within three years, not before. Id.

(2) Measuring "B Delay" for a National Stage Filing under 35 U.S.C. § 371

In addition to and independent of the "overlap" issue addressed above, Patentee respectfully submits that the Office did not apply the proper standard for determining the period of "B Delay" under 35 U.S.C. § 154(b)(1)(B). It is Patentee's understanding that for purposes of calculating "B Delay," the Office measured application pendency as beginning on September 17, 2004, the date on which the application fulfilled the requirements of 35 U.S.C. § 371. However, as detailed below, the relevant statutes and regulations require that when calculating "B Delay" for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that is 30 months from the priority date of the international application (i.e., September 19, 2004; not the date on which the application fulfilled the requirements of 35 U.S.C. § 371).

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the "actual filing date" of the application.

> (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States ... the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.
> 35 U.S.C. § 154(b)(1)(B). (emphasis added)

37 C.F.R. § 1.702(b) explains the meaning of the term "actual filing date" as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a national stage application begins

if the Office fails to issue a patent within three years after the date the national stage "commenced under 35 U.S.C. 371(b) or (f)."[1]

> (b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including... 37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application "commences."

> (b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. 35 U.S.C. § 371(b). (emphasis added)

> (f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371(f).

35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term "the treaty" refers to "the Patent Cooperation Treaty done at Washington, on June 19, 1970." See 35 U.S.C. § 351(a).

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[1] Consistent with 37 C.F.R. § 1.702(b), MPEP § 2730 states that "[i]n the case of an international application, the phrase 'actual filing date of the application in the United States' [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. 371(b) or (f)."

The articles of the Patent Cooperation Treaty cited in 35 U.S.C. § 371(b) are reproduced below.

Article 22

Copy, Translation, and Fee, to Designated Offices

(1) The applicant shall furnish a copy of the international application (unless the communication provided for in Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each designated Office not later than at the expiration of 30 months from the priority date. Where the national law of the designated State requires the indication of the name of and other prescribed data concerning the inventor but allows that these indications be furnished at a time later than that of the filing of a national application, the applicant shall, unless they were contained in the request, furnish the said indications to the national Office of or acting for the State not later than at the expiration of 30 months from the priority date. (emphasis added)

(2) Where the International Searching Authority makes a declaration, under Article 17(2)(a), that no international search report will be established, the time limit for performing the acts referred to in paragraph (1) of this Article shall be the same as that provided for in paragraph (1).

Article 39
Copy, Translation, and Fee, to Elected Offices

(1) (a) If the election of any Contracting State has been effected prior to the expiration of the 19th month from the priority date, the provisions of Article 22 shall not apply to such State and the applicant shall furnish a copy of the international application (unless the communication under Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each elected Office not later than at the expiration of 30 months from the priority date. (emphasis added)

"The applicable time limit" referred to in Patent Cooperation Treaty articles 22(1), 22(2), and 39(1)(a) is "the expiration of 30 months from the priority date." As a result, "the expiration of 30 months from the priority date" is the time at which the U.S. national stage commences

under the provisions of 35 U.S.C. § 371(b). This same conclusion as to the timing for commencement of the U.S. national stage is also summarized in MPEP § 1893.01.

> Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a). See 35 U.S.C. 371(b) and 37 CFR 1.491(a). PCT Articles 22(1), 22(2), and 39(1)(a) provide for a time limit of not later than the expiration of 30 months from the priority date. Thus, in the absence of an express request for early processing of an international application under 35 U.S.C. 371(f) and compliance with the conditions provided therein, the U.S. national stage will commence upon expiration of 30 months from the priority date of the international application. Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with the applicable requirements under 35 U.S.C. 371(c). MPEP § 1893.01. (emphasis added)

In view of the foregoing, the "actual filing date" of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating "B Delay" under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the date that is 30 months from the priority date of the international application.[2]

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

"A Delay"

A first PTO action was due on or before November 17, 2005 (the date that is fourteen months after September 17, 2004, the date on which the application fulfilled the requirements of 35 U.S.C. § 371). The PTO mailed the first non-final Office Action on January 9, 2008, thereby according a PTO Delay of 783 days. Patentee does not dispute the PTO's calculation for this "A Delay" from November 18, 2005 (the day after the fourteen-month anniversary of the date on which the application fulfilled the requirements of 35 U.S.C. § 371) to January 9, 2008. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

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[2] In contrast to reliance on "the expiration of 30 months from the priority date" for measuring "B Delay," the beginning of the relevant period for purposes of calculating "A Delay" is the date on which an international application fulfills the requirements of 35 U.S.C. § 371. See 35 U.S.C. § 154(b)(1)(A)(i)(II)and 37 C.F.R. § 1.702(a)(1).

A PTO action was due on or before September 7, 2008 (the date that is four months after May 7, 2008, the date on which a response to Office Action was filed). The PTO mailed a Notice of Allowance on October 6, 2008, thereby according a PTO Delay of 29 days. Patentee does not dispute the PTO's calculation for this "A Delay" from September 8, 2008 (the day after the date that is four months after the date on which a response to Office Action was filed), to October 6, 2008. See 37 C.F.R. §§ 1.702(a)(2) and 1.703(a)(2).

In view of the periods of "A Delay" detailed above, the total "A Delay" for this patent should be calculated as 812 days (i.e., the sum of 783 days and 29 days).

"B Delay"

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/SE03/00442, filed March 17, 2003, which claims the benefit of priority of Swedish Patent Application number 0200843-1, filed March 19, 2002.

The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(b), i.e., upon expiration of 30 months from the priority date of the international application. As a result, the date that the national stage commenced was September 19, 2004 (i.e., 30 months from the priority date of March 19, 2002).

The period beginning on September 20, 2007 (the day after the date that is three years after September 19, 2004, the date that the national stage commenced), and ending January 27, 2009 (the date the patent was issued), is 496 days in length.

"B Delay" may not include the number of days in the period beginning on the date on which a Notice of Appeal was filed and ending on the date of mailing of a Notice of Allowance. See 37 C.F.R. §§ 1.702(b)(4) and 1.703(b)(4). In the present application, no Notice of Appeal was filed.

In addition, "B Delay" may not include the number of days in the period beginning on the date on which a Request for Continued Examination was filed and ending on the date the patent was issued. See 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1). In the present application, no Request for Continued Examination was filed.

In view of the period of "B Delay" detailed above, the total "B Delay" for this patent is calculated as a total of 496 days. The PTO calculated 0 days of delay for issuance of a patent more than three years after filing. Patentee respectfully submits that the PTO's calculation of this "B Delay" is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 496 days.

Overlap of "A Delay" and "B Delay"

The "A Delay" and the "B Delay" overlap (i.e., occur on the same calendar day) for a total of 141 days from September 20, 2007 to January 9, 2008.

Applicant Delay

A reply to an Office Action was due on or before April 9, 2008 (the date that is three months after January 9, 2008, the date on which the Office Action was mailed). Patentee filed a response to the Office Action on May 7, 2008, thereby according an Applicant Delay of 28 days. Patentee does not dispute the PTO's calculation for this Applicant Delay from April 10, 2008 (the day after the date that is three months after the date on which the Office Action was mailed), to May 7, 2008. See 37 C.F.R. § 1.704(b).

Patentee filed an Information Disclosure Statement on August 1, 2008, subsequent to a reply filed on May 7, 2008. Patentee was not accorded any delay for a supplemental response. In good faith and candor, Patentee submits that the supplemental Information Disclosure Statement should have been accorded a total Applicant Delay of 86 days for delay from May 8, 2008 to August 1, 2008. See 37 C.F.R. § 1.704(c)(8).

In view of the periods of Applicant Delay detailed above, the total Applicant Delay for this patent should be calculated as 114 days (i.e., the sum of 28 days and 86 days).

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

In consideration of the events described above, Patentee believes that the PTA calculation of 784 days by the Office is incorrect. As such, Patentee respectfully requests reconsideration of the PTA in the following manner:

1) Total PTO Delay should be calculated as 1,167 days (i.e., the sum of 812 days of "A Delay" and 496 days of "B Delay" minus the 141 days of overlap);

2) Total Applicant Delay should be calculated as 114 days; and

3) Total PTA should be calculated as 1053 days.

The fee of $200 required under 37 C.F.R. § 1.18(e) is being submitted herewith. Please apply any other required charges to Deposit Account No. 06-1050, referencing Attorney's Docket No. 06275-0417US1.

Respectfully submitted,

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